

**Federal Communications Commission
Office of Engineering and Technology
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Title: Medical Body Area Network (MBAN) Measurement Procedures

Short Title: MBAN

Reason: Measurement procedures for MBAN devices subject to the rules in Part 95

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Keyword/Subject: Part 95, Medical Body Area Network (MBAN) Measurement Procedure

Question:

What measurement procedures should be used to demonstrate compliance with the Medical Body Area Network (MBAN) requirements in Part 95?

Answer:

See the measurement procedures in attachment [670572 D01 MBAN v01](#).

Attachment List:

[670572 D01 MBAN v01](#)

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**MEDICAL BODY AREA NETWORK (MBAN)
MEASUREMENT PROCEDURES**

I. INTRODUCTION

In May 2012, the Commission modified its existing Part 95 MedRadio rules to enable the deployment of MBAN devices in the 2360-2400 MHz band.¹ An MBAN is a low power network of sensors worn on the body controlled by a hub device that is located either on the body or in close proximity to it. MBAN devices operate on a secondary basis in the 2360-2400 MHz band – that is, they must not cause harmful interference to and must accept interference from Federal and non-Federal stations operating in the band in accordance with the Table of Frequency Allocations.

MBAN devices are low power networks that support wireless non-voice data communications between body-worn medical sensor (client) devices and a dedicated programmer/control (P/C) device. The sensor devices collect patient physiological information and/or deliver diagnostic and therapeutic functions. The P/C device aggregates the patient data that it receives from its associated sensors and transmits it to one or more monitoring stations via technologies that do not use the 2360-2400 MHz band (such as the hospital's local area network (LAN)).

The 2360-2400 MHz frequency band is authorized for use by MBAN devices; however, the Commission's rules require that MBAN operations in the 2360-2390 MHz be registered and coordinated to ensure that Aeronautical Mobile Telemetry (AMT) operations in this band are protected from harmful interference.² MBAN devices in the 2360-2390 MHz band may be used only indoors within a health care facility, while MBAN devices in the 2390-2400 MHz band may be used anywhere.³ MBAN devices in the 2360-2390 MHz band must comply with a control message that notifies the P/C device(s) to limit transmissions to coordinated frequencies or to cease operation on frequencies within this band segment. The control message will be provided by an FCC-designated MBAN Frequency Coordinator that will

¹ Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, *First Report and Order and Further Notice of Proposed Rulemaking*, ET Docket No. 08-59, FCC 12-54, 27 FCC Rcd 6422 (2012).

² MBAN devices that are designed to operate exclusively within the 2390-2400 MHz band do not require registration and coordination.

³ The Commission requires that entities preparing to use the 2390-2400 MHz band with equipment that is capable of also operating in the 2360-2390 MHz band and who are eligible to operate MBAN systems in the 2360-2390 MHz band register the MBAN system regardless of whether they have any current intent to eventually use the 2360-2390 MHz band capacity of their equipment.

notify a control point, unique to each health care facility, of the frequencies available in the 2360-2390 MHz band at that facility. The Control Point uses this information to generate a control message to convey the available frequencies to the MBAN P/C device(s) via technologies that do not use the 2360-2400 MHz band (typically, the hospital's LAN). The P/C devices then use this information to enable their associated MBAN sensors on the coordinated frequencies. A P/C device shall not commence operating and shall automatically cease operating in the 2360-2390 MHz band if it does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation.⁴

II. SYSTEM COMPONENTS

A. Body-worn Sensor Devices

The body-worn (or body-proximity) sensors devices associated with an MBAN measure and collect the individual patient data and transmit the data to their dedicated P/C device.⁵ The P/C device informs the sensors as to what frequencies are available for use based on information provided via the control message generated by the MBAN Control Point. In the event of a failure to receive the control message the sensors must immediately cease transmission on frequencies within the 2360- 2390 MHz band.

B. Programmer/Controller (P/C) Devices

The programmer/controller device collects data from the sensor devices and manages its transmission outside the MBAN network. The P/C device also receives a control message from a control point (typically, via the facility LAN) and uses the embedded information to enable the associated sensors to operate on coordinated frequencies in the 2360-2390 MHz band segment. In the event of a failure to receive a control message, the P/C device must immediately inform its sensor devices to cease transmission on frequencies within the 2360-2390 MHz band.

C. Control Point

The Control Point receives communications from the MBAN Frequency Coordinator (via secure E-Key,⁶ email, telephone, fax, etc.) informing what, if any, frequencies within the 2360-2390 MHz band are available at that particular location/facility for use to establish the MBAN. This information is used to generate a control message that is provided to the P/C devices in the MBAN (typically, via facility LAN) notifying them of those frequencies available for use.

There is typically only one Control Point per coordinated facility. From an FCC equipment certification perspective, the Control Point is technically not a part of the MBAN; however, the control messages

⁴ In that case, the P/C devices will have the option to operate in the 2390-2400 MHz band.

⁵ While a system design that embodies direct communications between the programmer/control transmitter and an associated body-worn device would certainly comply with this section, the Order on Reconsideration and Second Report and Order, ET Docket No. 08-59, FCC 14-124, does not diminish the flexibility that manufacturers have to design other types of system architectures to meet this requirement. This includes, for example, an MBAN system in which a body-worn device that is serving as a "coordinator node" provides intermediate communications between the programmer/control transmitter and the other body-worn devices that are part of the same system of MBAN body-worn devices deployed on a patient. In this case, MBAN device operation still remains dependent upon the programmer/control transmitter receiving an acceptable control signal.

⁶ The term E-key refers to "electronic key," which is a data message that specifies and enables use of specific frequencies by the MBAN devices (FCC 12-54, paragraphs 10, 72).

generated by a Control Point are necessary for testing MBAN functionality. Therefore, a simulated Control Point must be provided by the applicant to generate a valid control message for delivery via a representative local area network connection to the MBAN P/C to enable operation on frequencies within the 2360-2390 MHz band.

III. TECHNICAL REQUIREMENTS

The FCC technical requirements applicable to the sensor/actuator and P/C devices comprising an MBAN can be subdivided into four distinct categories - electromagnetic compatibility (EMC) requirements, frequency coordination requirements, labeling requirements, and RF exposure requirements.⁷ This document provides guidance on EMC requirements and frequency coordination requirements only. Compliance testing and validation guidance is provided in Clauses IV), V), and VI), for the technical requirements summarized in this clause.

A. EMC Requirements

1. Section 95.628(d)(2) Frequency Stability Requirements

All MBAN devices must maintain a frequency stability of ± 100 ppm over a temperature range of 0 °C to 55 °C.

2. Section 95.633(e) Emission Bandwidth Limits

All transmissions associated with an MBAN are limited to an emission bandwidth (EBW) of less than or equal to 5 MHz, where the EBW is determined by measuring the width of the signal between points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. Multiple transmission channels from a single device are permitted as long as the total emission bandwidth used by all devices in any single patient MBAN communication session does not exceed the maximum authorized bandwidth of 5 MHz.

3. Section 95.639(f) Maximum Transmitter Power Limits

MBAN transmissions in the 2360-2390 MHz frequency band are limited to a maximum equivalent isotropic radiated power (EIRP) that shall not exceed the lesser of 1 mW (0 dBm) or $10\log(\text{EBW})$ dBm, where EBW is expressed in MHz. MBAN transmissions in the 2390-2400 MHz frequency band are limited to a maximum EIRP that shall not exceed the lesser of 20 mW (13 dBm) or $16 + 10\log(\text{EBW})$ dBm, where EBW is expressed in MHz.

4. Section 95.635(d) Unwanted Radiation Limits

The EIRP levels (expressed within a 1 MHz bandwidth) associated with all MBAN emissions on frequencies within the first 2.5 MHz relative to the edges of the 2360-2400 MHz frequency band (*i.e.*, between 2357.5 and 2360.0 MHz, and between 2400.0 and 2402.5 MHz) must be attenuated by at least 20 dB relative to the maximum EIRP level (within any 1 MHz) of the fundamental emission (*i.e.*, 20 dBc). The field strength levels associated with all MBAN emissions on frequencies beyond the first 2.5 MHz relative the edges of the 2360-2400 MHz frequency band (*i.e.*, between 30 MHz and 2357.5 MHz, and between 2402.5 MHz and the tenth harmonic of the highest fundamental frequency) must be less than or

⁷ Basic guidance on labeling and RF exposure evaluation is given in KDB Publication 784748 and KDB Publication 447498, respectively.

equal to those limits shown in Table 1 when measured at a distance of 3 m (the more restrictive limit applies at each frequency range transition).

Table 1—Field strength limits

Frequency (MHz)	Field Strength Limit ($\mu\text{V/m}$)	Field Strength Limit ($\text{dB}\mu\text{V/m}$)
30-88	100	40.0
88-216	150	43.5
216-960	200	46.0
960 and above	500	54.0

The emission limits shown in Table 1 are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz.

B. Section 95.628(c) Frequency Coordination Requirements

An MBAN transmitter shall not commence operation and shall automatically cease operation in the 2360-2390 MHz band if it does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation. Additionally, an MBAN transmitter operating in the 2360-2390 MHz band shall comply with a control message that notifies the device to limit its transmissions to segments of the 2360-2390 MHz band or to cease operation in the band.

IV. COMPLIANCE TEST AND VALIDATION BASIC CONSIDERATIONS

A. General Considerations

- a) Samples submitted for compliance testing shall be fully representative of the products intended for end user installation and operation.
- b) The compliance tests will often necessitate the establishment of a communications link between the P/C device and one or more associated body-worn sensor devices while measuring the emissions from either the P/C device or a body-worn sensor device.
- c) A control point with proper test software must be provided that is capable of generating a valid control message, utilizing the applicable network protocols, and delivering it to the MBAN P/C device via a local area network connection for the purpose of enabling or restricting operation on frequencies within the 2360-2390 MHz band. The control point shall provide the ability for test personnel to set relevant control message parameters (*e.g.*, channel frequency list, available or restricted sub-band list, transmitter power) to facilitate testing.⁸ The preferred test method for MBAN devices is bench testing, unless *in situ* testing is required due to the unique design and functionality of the device. Manufacturers and test organizations should submit inquiries to seek out guidance on appropriate *in situ* testing.

⁸ Along with the device submitted for compliance test, operational descriptions of each device should be provided that fully explains the functions of each unit in the network, sequence of operation, as well as any unique features that the manufacturer may have implemented in their design.

- d) For MBAN devices with a non-removable integrated power source (e.g., body-worn sensor device), the manufacturer shall provide information with regards to activating and deactivating the device.
- e) An MBAN device type shall be declared as a body-worn sensor device, a P/C device, or both (e.g., an MBAN device that can be configured in either mode).
- f) Acknowledging the unique design of MBAN devices, a system function test maybe required to ensure each component in the network meets the requirement as specified in the rulemaking. The system function test also verifies the proper operation of the components that at times play different roles, such as a sensor that may also function as a sensor hub.

B. Test Site Considerations

Because specific antenna(s) must be tested and supplied with an MBAN device per § 95.639(f)(5), it will be necessary to perform the compliance measurements using a radiated test set-up. Radiated emission measurements shall be made in an environment that ensures valid, repeatable test data.

An outdoor test site should be an open, flat, level area that is clear of overhead wires and reflecting structures and is sufficiently large to permit measuring antenna placement at the specified distance. Adequate spacing shall also be provided between the site, including the DUT and the measuring antenna, and any adjacent, large reflecting structures. Reflecting structures are defined as objects or housings that are conductive or become conductive over time. Alternatively, an anechoic chamber of appropriate size and frequency specification can serve as a valid test site.

Radiated emission test sites should be validated by measurement of the attenuation of signals propagated over the site and compared with theoretical attenuation of horizontally or vertically polarized signals propagated over an ideal site.

When performing radiated emissions tests, the DUT-to-test antenna orientation that produces the maximum received signal amplitude level should be determined by rotating the DUT through 360° while varying the receive antenna in height and polarization until the maximum signal amplitude is found.

C. Number of Fundamental Frequencies to be tested in DUT Transmit Band

Measurements of MBAN devices shall be performed and, if required, reported for each band in which the DUT can be operated with the device operating at the number of frequencies in each band specified in the following table.

Table 2—Number of fundamental frequencies for testing

Frequency Range in which device operates	Number of Frequencies	Location in Frequency Range
1 MHz or less	1	Middle
1 MHz to 10 MHz	2	1 near top and 1 near bottom
More than 10 MHz	3	1 near top, 1 near middle and 1 near bottom

V. EMC MEASUREMENT PROCEDURE GUIDANCE

A. Frequency Stability Measurement

Measurements shall be performed over the specified temperature ranges (see III) A) 1)) to demonstrate compliance with the frequency stability requirements specified in § 95.628(d). The following procedures can be used to demonstrate compliance with the requirements specified in § 95.628(d).

- a) Supply the DUT with a nominal ac voltage or install a new or fully charged battery in the DUT. If possible, a dummy load shall be connected to the DUT, because an antenna near the metallic walls of an environmental test chamber could affect the output frequency of the DUT. If the DUT is equipped with a permanently attached, adjustable-length antenna, then the DUT shall be placed in the center of the chamber with the antenna adjusted to the shortest length possible.
- b) Turn ON the DUT and tune it to one of the number of frequencies shown in IV) C).
- c) Couple the DUT output to the measuring instrument by connecting an antenna to the measuring instrument with a suitable length of coaxial cable and placing the measuring antenna near the DUT, or by connecting a dummy load to the measuring instrument, through an attenuator if necessary.
- d) Adjust the location of the measurement antenna and the controls on the measurement instrument to obtain a suitable signal level (*i.e.*, a level that will not overload the measurement instrument but is strong enough to allow measurement of the operating or fundamental frequency of the DUT).
- e) Turn the DUT OFF and place it inside the environmental temperature chamber. For devices that have oscillator heaters, energize only the heater circuit.
- f) Set the temperature control on the chamber to the highest specified in III) A) 1) and allow the oscillator heater and the chamber temperature to stabilize.
- g) While maintaining a constant temperature inside the environmental chamber, turn the DUT ON and record the operating frequency at startup, and at 2 minutes, 5 minutes, and 10 minutes after the DUT is energized. Four measurements in total are made.
- h) Measure the frequency at each of frequencies specified in V) C).
- i) Switch OFF the DUT but do not switch OFF the oscillator heater.
- j) Lower the chamber temperature by not more than 10 °C, and allow the temperature inside the chamber to stabilize.
- k) Repeat step g) through step j) down to the lowest specified temperature.

B. Emission Bandwidth Measurement

Refer to KDB Publication 558074 for proper emission bandwidth measurement. Either of the two options 8.1 and 8.2 can be implemented as described in the document.

C. Maximum EIRP Measurement

Follow the procedure explained in section 9.0 of KDB publication 558074 to measure maximum peak conducted power. Determine the EIRP by adding the ideal free-space propagation path loss to the measured received power level.

D. Unwanted Radiation Measurement

1. Measurement of Unwanted Emission Levels in the First 2.5 MHz Relative to the Authorized Band (2357.5-2360.0 MHz and 2400.0-2402.5 MHz)

- a) Tune analyzer to the center frequency of the authorized MBAN frequency band (*i.e.*, 2380 MHz).
- b) Set analyzer to span from a lower frequency of 2350 MHz to a upper frequency of 2410 MHz. (Note: Measurements performed outside of an anechoic chamber may be influenced by environmental RF energy from emitters other than the DUT – in particular in the 2400-2410 MHz frequency range.)
- c) Set the RBW = 1 MHz.
- d) Set VBW \geq 3 MHz.
- e) Sweep time = auto couple.
- f) Number of sweeps = free run.
- g) Detector = peak.
- h) Trace mode = max hold.
- i) Configure DUT to transmit on a channel or sub-band closest to the 2360 MHz lower band-edge.
- j) For a radiated measurement, maximize the signal amplitude levels in 2350-2360 MHz by rotating DUT and varying the measurement antenna height and polarization.
- k) Allow trace to fully stabilize (maximize).
- l) Use a peak marker to mark the peak amplitude over the received channel bandwidth.
- m) Use a second peak marker to mark the peak amplitude over the 2357.5-2360.0 MHz frequency range.
- n) Determine the delta between the markers.
- o) Compare delta to the 20 dBc limit.
- p) Retune DUT to highest frequency channel (closest to upper band edge of 2400 MHz).
- q) Reset max hold.
- r) For a radiated measurement, maximize the signal amplitude levels in 2350-2360 MHz by rotating DUT and varying the measurement antenna height and polarization.
- s) Allow new trace to fully stabilize (maximize).
- t) Use a peak marker to mark the peak amplitude over the received channel bandwidth.
- u) Use a second peak marker to mark the peak amplitude over the 2400.0-2402.5 MHz frequency range.

- v) Determine the delta between the markers.
- w) Compare delta to the 20 dBc limit.

Note: It is not necessary to convert from measured received power to EIRP to demonstrate compliance because the limit is expressed in dBc.

2. Measurement of Unwanted Emission Levels beyond the First 2.5 MHz Relative to the Authorized Band (30-2357.5 MHz and 2402.5 MHz to the 10th harmonic of the highest fundamental frequency)

Use peak detector on first-level scan. If no measured emissions are found that exceed applicable limits (even when quasi-peak or average detector is specified) then compliance has been demonstrated. If emissions are found that exceed the applicable limit, then the measurement can be repeated using the specified quasi-peak detector (for emissions on frequencies ≤ 1 GHz) or average detector (for emissions on frequencies > 1 GHz) on the isolated non-compliant emissions.

Measurements of unwanted emissions, particularly at frequencies well beyond the fundamental emission, may require the use of pre-amplifiers or measurement distances less than the specified 3 m to resolve measurement dynamic range limitations. Measurements performed at distances less than the 3 m specification are permitted, but they must not be performed at distances that precede the far field region of the DUT. If a pre-amplifier is used, then the measured amplitude levels must be adjusted accordingly.

Note that radiated field strength measurements performed outside of an anechoic chamber may be influenced by existing environmental RF energy. If environmental emissions that exceed the relevant limits are included in the measurement results, then a clear explanation for how they were isolated from consideration shall be provided.

- a) Maximize DUT emissions by optimizing azimuth, elevation and polarization relative to DUT.
- b) Set analyzer lower frequency to 30 MHz and upper frequency to 960 MHz.
- c) Set RBW = 100 kHz and VBW \geq 300 kHz.
- d) Set detector = peak.
- e) Trace mode = max hold.
- f) Sweep time = auto set.
- g) Number of sweeps = free run.
- h) Reset max hold.
- i) Allow sufficient time for trace to maximize.
- j) Use peak marker to identify the frequency and amplitude associated with the three highest emissions within the specified bandwidths (*i.e.*, 30-88 MHz, 88-216 MHz and 216-960 MHz) and record the data.
- k) Reset analyzer lower frequency to 960 MHz and upper frequency to 2357.5 MHz.
- l) Reset RBW = 1 MHz and VBW \geq 3 MHz.
- m) Reset max hold.
- n) Allow sufficient time for trace to maximize.
- o) Use peak marker to identify the frequency and amplitude associated with the six highest emissions and record the data.

- p) Reset analyzer lower frequency to 2402.5 MHz and the upper frequency to the maximum tenth harmonic frequency relative to the fundamental emission.
- q) Reset max hold.
- r) Allow sufficient time for the trace to maximize.
- s) Use peak marker to identify the frequency and amplitude associated with the six highest emissions and record the data.
- t) Adjust recorded data to account for any pre-amplifier gain and cable losses.
- u) Convert the resultant amplitude levels to field strength levels (see, e.g., KDB Publication 412172).
- v) Compare to applicable field strength limit.
- w) Isolate any non-compliant emissions, and unless they can be demonstrated not to be associated with the DUT, utilize the detector applicable to the frequency range (*i.e.*, quasi-peak or average) to demonstrate compliance with the relevant limit.

VI. FREQUENCY COORDINATION ATTESTATION REQUIREMENTS AND VALIDATION TESTS

A. Written Attestation

MBAN manufacturers must attest to the details of controlling MBAN device access to the 2360-2390 MHz band. This written attestation shall at a minimum include:

- a) Description of the information conveyed by a valid control message (*e.g.*, channel frequency list, available/restricted sub-bands, transmitter power, etc.).
- b) Description of the mechanism(s) used to distribute the control to all of the MBAN devices within a qualifying health care facility.
- c) Definition of the control message periodicity (maximum and minimum time between transmissions of valid control message).
- d) Description of any additional mechanisms that limit use of the 2360-2390 MHz band to indoor use.

B. Tests to Validate Compliance to Requirements of § 95.628(c)

1. Verify that P/C transmitter does not transmit on frequencies within the 2360-2390 MHz band until a valid control message is received

- a) Set up a LAN connection between the MBAN DUT (P/C device) and simulated control point.⁹
- b) Disable the control message to the DUT.
- c) Apply power to DUT.

⁹ A simulated control point must be capable of generating a valid control message, utilizing the applicable network protocols, and delivering it to the MBAN P/C device via a local area network connection for the purpose of enabling or restricting operation on frequencies within the 2360-2390 MHz band. The simulated control point shall provide the ability to test personnel to set relevant control message parameters (*e.g.*, channel frequency list, available or restricted sub-band list, transmitter power) to facilitate testing.

- d) Verify that DUT does not commence transmissions on frequencies in the 2360-2390 MHz band.
- 2. Verify that P/C transmitter operates on frequencies in the 2360-2390 MHz band only in accordance with instructions contained within a valid control message**
- a) Establish LAN connection between DUT and simulated control point.
 - b) Set control message frequency/channel/sub band parameters to enable operation as per manufacturer definition.
 - c) Verify that DUT transmissions in the 2360-2390 MHz band are in accordance to the control message specifications.
 - d) Reset control message to prohibit operation on frequencies within the 2360-2390 MHz band.
 - e) Verify that DUT ceases transmission on frequencies within the prohibited band with a latency period not exceeding the maximum control message periodicity.
 - f) Reset control message to enable DUT operation on frequencies within the 2360-2390 MHz band.
 - g) Verify that the DUT resumes transmitting on frequencies within the 2360-2390 MHz band.
 - h) Disrupt (disable) the control message.
 - i) Verify that DUT ceases all transmission on frequencies within the 2360-2390 MHz band.
- 3. Verify that body-worn sensor transmitters cease transmitting in the 2360-2390 MHz band when connection is lost with the associated P/C device**
- a) Establish a LAN connection between the MBAN P/C device and the simulated control point.
 - b) Establish connection between the MBAN P/C and the body-worn sensor device under test (DUT).
 - c) Configure the control message to enable operation in the 2360-2390 MHz band.
 - d) Verify that transmissions between DUT and its associated MBAN P/C are consistent with the control message configuration.
 - e) Interrupt the RF verify that the DUT ceases transmission in the 2360-2390 MHz band.